IDeA States Pediatric Clinical Trials Network

Pre-Application Webinars for the Clinical Sites for the
"ECHO IDeA States Pediatric Clinical Trials Network - 2 (RFA-OD-19-026)" and
"Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (RFA-OD-19-025)"
https://www.nih.gov/echo/funding

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Office of the Director, National Institutes of Health

11 October 2019 & 23 October 2019

Purpose

- (1) familiarize the potential applicant with established **NIH guidelines** and criteria for review;
- (2) discuss the areas of **NIH programmatic emphasis;**
- (3) facilitate the submission of a **well-organized application**

- Welcome/Introduction
  - Dr. Maribeth Champoux (CSR)
  - Mr. Bryan Clark (NICHD)
  - Ms. Bonnie Jackson (NICHD)
- ECHO
  - ECHO ISPCTN Mission
  - ECHO High-level Overview
  - ECHO Focus Area
- IDeA States Pediatric Clinical Trials Network (ISPCTN)
  - RFAs Major Highlights
  - Deadlines
  - Questions

U24 Mechanism

Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (U24 Clinical Trial Required - Infrastructure)

U24	**Cooperative Agreements**: Support mechanisms that **NIH** frequently uses for high-priority research areas that require a level of involvement from **NIH** staff that is higher than for a typical research project (R) grant	Resource-Related Research Projects--Cooperative Agreements	To support research projects contributing to improvement of the capability of resources to serve biomedical research

https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UG1&Search.x=0&Search.y=0&Search_Type=Activity

UG1 Mechanism

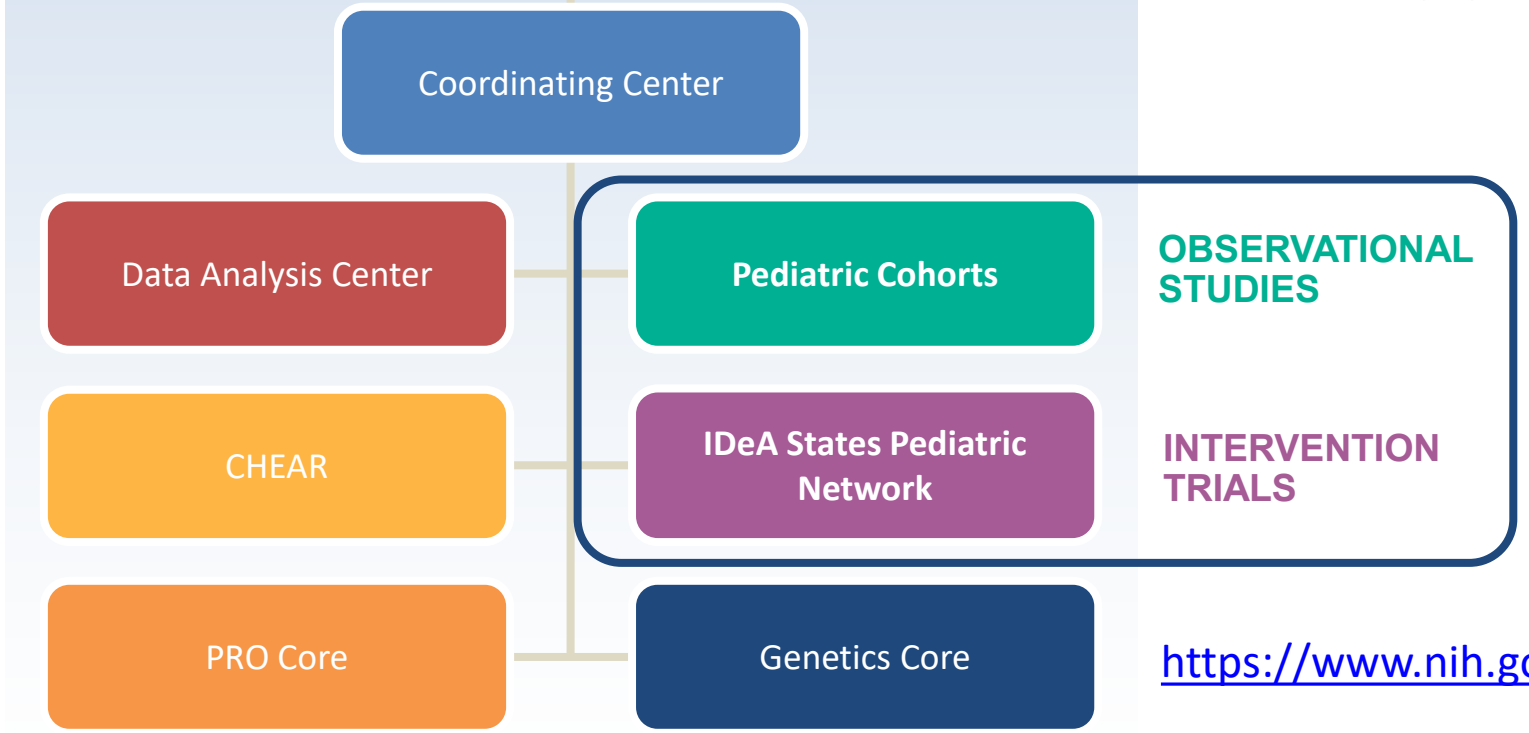
Clinical Sites for the ECHO IDeA States Pediatric Clinical Trials Network - 2
(UG1 Clinical Trial Required)

Cooperative Agreements	Clinical Research Cooperative Agreements -- Single Project	To support single project applications conducting clinical evaluation of various methods of therapy and/or prevention (in specific disease areas). Substantial federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of the award

https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UG1&Search.x=0&Search.y=0&Search_Type=Activity

How is ECHO Structured?

ECHO components



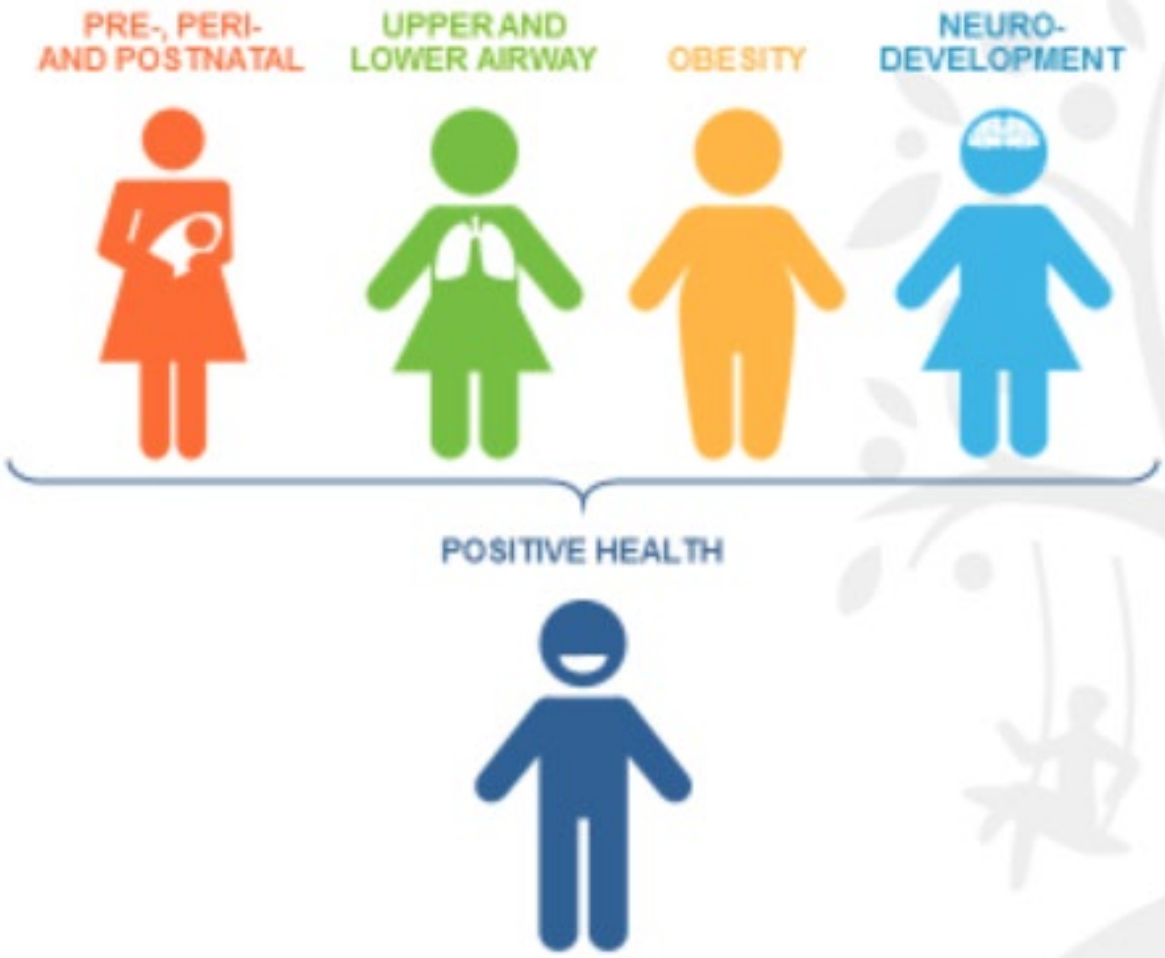
https://www.nih.gov/echo/program-components

ECHO Mission

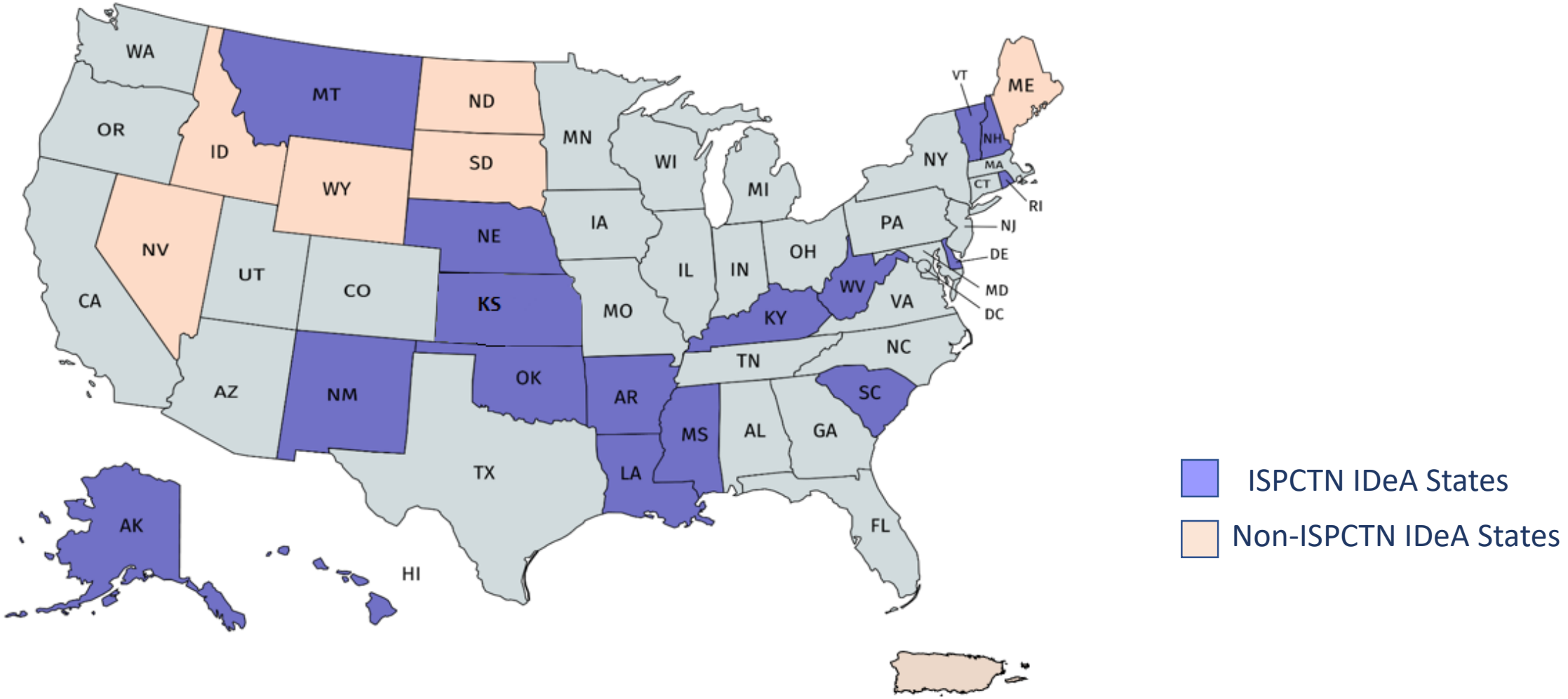
Enhance the health of children for generations to come

ECHO's Health Outcomes

Focus on key pediatric outcomes that have a high public health impact throughout childhood and adolescence



Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN)



IDeA States Pediatric Clinical Trials Network Overall Goals

Provide access to state-of-the-art clinical trials to

- Medically underserved and rural populations in the five ECHO priority areas

Build national pediatric research capacity

- To conduct clinical trials by providing professional development for faculty, team support, and infrastructure building
- To compete for future funding

IDeA States Pediatric Clinical Trials Network
Projects Underway

- Pharmacokinetics of Understudied Drugs in Children (POPS01)
  - ClinicalTrials.gov Identifier: NCT01431326

    https://clinicaltrials.gov/ct2/show/NCT01431326?term=NCT01431326&rank=1
  - 19 ISPCTN sites

- Vitamin D regimen for children with asthma and obesity (VDORA)
  - ClinicalTrials.gov Identifier: NCT03686150

    https://clinicaltrials.gov/ct2/show/NCT03686150?term=NCT03686150&rank=1
  - 15 ISPCTN sites

- Healthy Lifestyle Program (iAmHealthy)
  - 4 ISPCTN Sites

- Advancing Clinical Trials for Neonatal Opioid Withdrawal Syndrome (ACT NOW)
  - ESC ClinicalTrials.gov Identifier: NCT04057820

    https://clinicaltrials.gov/ct2/show/NCT04057820?term=NCT04057820&rank=1
  - 12 ISPCTN Sites (ESC)
  - 8 ISPCTN Sites (Weaning)

Requests for Applications (RFA)

- **RFA-OD-19-025**
  - Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (U24 Clinical Trial Required - Infrastructure)
  - **Pay close attention to the:**
  - Details of Section III
    - » Personnel must haves
  - Details of Section IV
    - » Professional development plan
    - » Clinical trial protocol and development and implementation plan

- **RFA-OD-19-026**
  - Clinical Sites for the ECHO IDeA States Pediatric Clinical Trials Network - 2 (UG1 Clinical Trial Required)
  - **Pay close attention to the:**
  - Details of Section III
    - » Personnel must haves
  - Details of Section IV
    - » Provide the specific pediatric population
    - » Senior/Key Person Profile
    - » Professional development plan
    - » Clinical trial protocol and development and implementation plan

RFA-OD-19-025

https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-025.html

Eligibility of DCOC PD/PI

- Must have prior expertise in operating a data coordinating center in multicenter studies in the previous five years

- Should have (together, the DCOC PD/PI and staff) the following minimum qualifications in terms of experience and expertise in:

  -Planning, developing and executing pediatric studies, and the special consent and IRB procedures needed for the conduct of research in children, is strongly preferred

  -Conducting clinical trial study design and having statistical expertise including pragmatic clinical trial methodology

  -Designing data collection systems

  -Working with a variety of stakeholders

Collaboration

- Partnerships are encouraged to strengthen any aspect of DCOC performance
- All partnerships must be well-justified
- If partnerships with institutions outside of IDeA states are proposed, ***a minimum of 60% of total costs must be awarded to institutions within IDeA states***

Professional Development Plan

- Describe plans to provide general professional development opportunities to **Network DCOC and Clinical Site personnel.**

- *Propose structure and content for a **Clinical Trial Skills Development Core** to enhance knowledge/performance of a Clinical Site Investigator team on core protocol development skills including (but not limited to)*
  - articulating a clinical trial research question based on health impact for children and a research gap analysis
  - justification for multi-center network to meet study objectives
  - designing an intervention

- Clinical Trial Skills Development Core
  - Include senior faculty level-led educational opportunities, including didactic and interactive training in multicenter clinical trial protocol development
  - Develop a curriculum adapted to the needs of the research team at clinical sites

Clinical Trial Protocol Development and Implementation Plan

- Provide a plan for how clinical trials will be developed, implemented, and monitored in collaboration with the Clinical Sites
- Assist in protocol development
- Describe plans for protocol training of research staff at the Clinical Sites
- Describe plans for oversight of data collection, transfer, and management

RFA-OD-19-026

https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-026.html

Eligibility of Site PD/PI

- PD(s)/PI(s) from IDeA states might not have extensive experience with clinical trials or have comparable track records of publications and funding as more experienced investigators
  - *However*, the PD(s)/PI(s) must be capable of providing both administrative and scientific leadership to the development and implementation of the proposed program

- PD(s)/PI(s) for the Clinical Site should be a board-certified Pediatrician

- PD(s)/PI(s) will supervise the development and conduct of ISPCTN clinical research at their institution and/or partner Clinical Site

Collaboration

- Applicants are encouraged to propose collaboration:
  - IDeA Program-Infrastructure for Clinical and Translational Research (IDeA-CTR) awardee
  - Clinical and Translational Science Award program in their own state or in another IDeA state
  - Other ECHO components or investigators

- **<u>NOTE</u> -** ***NIH will award a minimum of 60% of total costs to institutions within IDeA states.***

Clinical Sites Access to Target Populations

- Must describe their access to community practices that serve a minimum of 30 percent children from rural homes

- Provide the specific pediatric population available for study by the Clinical Site. *Include information for the year 2018 in tabular format:*
  - The number and percent of children living in a rural area
  - The number of births in your Clinical Site's hospital (or hospitals)
  - The number of discharges from your Clinical Site's hospital (or hospitals) with a diagnosis of asthma

- See RFA for additional requested data

Senior/Key Person Profile

- At least one PD(s)/PI(s) must be a fully qualified, Board Certified pediatrician (no less than 1.8 person-months for each year of the five-year award)

- One Senior Faculty Development Leader should be designated as a Senior/Key person,(a minimum of 0.6 person-months for each year of the five year award)

- One or two Junior Faculty should be designated as key persons (a minimum of 1.8 person-months per year for each faculty member included). *An institutional commitment of at least 1.8 person-months per year for each junior faculty member included should be described in a letter of support*

- Research Nurse Coordinator(s) should reflect qualifications through training, background and research experience (no less than a total of 12 person-months for each year of the five-year award). *Additional part-time research coordinators needed for research may be included in the application*

Research Plan

- **Subsection 2: Readiness for clinical trials**
  - To engage in a multicenter clinical trials network, including ability to develop and implement multicenter clinical trials, research infrastructure, and trial recruitment infrastructure

- **Subsection 3: Clinical research skills development plan**
  - Propose a robust capacity building plan for clinical research skills development of junior faculty, senior faculty, and research coordinators that are included in the grant
  - Knowledge and skills development should focus on clinical research design and implementation
  - Applicants are encouraged to partner with other institutions to provide needed expertise to guide and provide clinical research skills development

Research Plan

- **Subsection 4: Rural engagement plan**
  - Propose a strategy to recruit rural participants into one or more ISPCTN trials
  - Describe the approach to recruiting participants from rural areas
  - Applicants may collaborate with other institutions and entities to allow rural recruitment

- **Subsection 5: Clinical Trial Proposal**
  - Propose one multicenter clinical research trial that the ISPCTN will conduct during the funding cycle
  - The trial should focus on one of the five focus areas of the ECHO program
  - The proposal should be feasible within the funding cycle

Important Date for the RFA

Letters of Intent due

November 2, 2019

Application due

December 2, 2019

Questions/Concerns/Comment…

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Note: Please put in your **email subject line the RFA** that you are referring to RFA-OD-19-025 and/or RFA-OD-19-026